REMARKS/ARGUMENTS

Claims 1, 2 and 15 are pending in the instant application. Claim 1 has been amended, support for which may be found at page 8, lines 21 through 25, and elsewhere within applicant's specification, as originally filed.

The Examiner has rejected claims 1, 2 and 15 under 35 U.S.C. 103(a) as being unpatentable over Yoon et al., U.S. Patent No. 4,981,149, in view of Hubbard et al., U.S. Patent No. 3,308,820 and further in view of McGregor et al., U.S. Patent No. 5,649,961. The rejection of applicant's claims is respectfully traversed. Reconsideration and favorable action is respectfully solicited in view of the following.

The Examiner has rejected claims 1, 2 and 15 under 35 U.S.C. 103(a) as being unpatentable over Yoon et al., U.S. Patent No. 4,981,149, in view of Hubbard et al., U.S. Patent No. 3,308,820 and further in view of McGregor et al., U.S. Patent No. 5,649,961. The Examiner is of the view that:

> Yoon teaches a hollow suturing needle (60) having a yielding moment and an internal cavity wherein a drug to be dispensed can be released by holes extending through walls communicating with the lumen and sealed in the suture needle by attachment of suture material which does not extend the length of the lumen, and wherein the fluid may be an antibiotic (Column 7, proximate lines 4-20). Yoon teaches the suture needle having a non-linear relationship between the cross-sectional area of the internal cavity and the yielding moment (this is inherent as the distal end of the needle is not hollow, and the proximal end is hollow, therefore the relationship between the cross-sectional area and the yielding moment will be non-linear).
>
> Yoon fails to teach a compressed gas residing between the fluid and the non-hollow portion or seal. Hubbard teaches a device having an internal cavity therein comprising: a proximal end (18), a distal end (16), a point on the distal end (fig. 2), an opening at or in the proximity of the distal end, and a non-hollow portion or seal at or adjacent to the proximal end (16); wherein the internal cavity is in fluid communication with said opening at one end and terminates at said non-hollow portion or seal at the other end (fig. 1); a

fluid (M) residing within the internal cavity; and a compressed gas (G) residing between the fluid (M) and the non-hollow portion or seal (18), (Columns 3-4, proximate lines 60-75 and 1-5 respectively), in order to provide a disposable fluid dispensing device that is simple to manufacture and provides effective ejection of medicine from the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Yoon with the pressurized gas ejection mechanism of Hubbard in order to provide a disposable needle that is simple to manufacture and provides effective ejection of medicine from the device.

The combination of Yoon and Hubbard fails to teach wherein the suture is formed of metal. McGregor teaches a suture needle wherein the needle is formed of metal in order to provide a material having sufficient strength-to perform procedures without breakage or deformation. It would have been obvious to one of ordinary skill in the art a the time the invention was made to modify the combination of Yoon and Hubbard with a needle made of metal for non-endoscopic procedures such as suturing skin in order to provide a needle with sufficient strength to perform procedures without breakage or deformation. The limitation wherein the device is made of metal tubing is being treated as a product by process limitation, in that the "wherein the suture needle is produced from metal tubing" refers to the process of making the device and not to the final product created. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP §2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

It appears the product disclosed by the combination of Yoon, Hubbard and McGregor would be the same and would perform equally well as that claimed; especially since both applicant's product and the prior art have the same final shape and structure of a needle being formed from tubing, i.e. having a channel there through.

Yoon et al., U.S. Patent No. 4,981,149, proposes bioabsorbable suture devices for use in endoscopic surgery. The proposed devices include a suture needle made of bioabsorbable material for pulling a length of suture material through bodily tissue, allowing the suture needle to be inadvertently or intentionally

left in the tissue, and a suture needle having a length of suture material attached thereto with a contractible loop or passage at the proximal end of the suture material to allow the suture needle to be passed therethrough, the loop or passage contracting to clamp or grip the suture material to function similar to a conventional tied suture knot.

Yoon teaches at col. 3, lines 13-19 that an "object of the present invention is to construct a suture needle of the type attached to a length of suture material ... of a bioabsorbable material such that, should the suture needle be dropped or lost during endoscopic surgery, open surgery is not required to remove the needle. Yoon teaches further at col. 3, lines 20-24 that a "further object ... is to facilitate attachment of a length of suture material to a suture needle made of bioabsorbable material by using the plastic characteristics of the bioabsorbable material." [Emphasis added].

Hubbard et al., U.S. Patent No. 3,308,820, proposes a disposable medicinal hypodermic syringe that is said to have utility in the administration of a liquid medicament. The disposable medicinal hypodermic syringe is a single unitary structure having a sealed vial unit containing a charge of liquid medicine or other liquid to be injected into the patient's tissue under sealed gas pressure; a hollow injection needle or cannula; and a mechanically stabilized, transparent and flexibly compressible aspiration sleeve or tube unit sealingly applied between the vial unit and the cannula, for checking by vacuum inducement against the possibility that the cannula has penetrated a blood vessel, prior to the discharge of the medicine under gas pressure into muscular tissue. The syringe may also be used for intravenous injection.

McGregor et al., U.S. Patent No. 5,649,961, proposes a process for the manufacture of suture needles and, more particularly, a process for enhancing the

physical strength of the suture needles through an expedient cold-working or cold-forming procedure. Also disclosed is the provision of a physically strengthened suture needle, particularly a surgical suture needle possessing a curvilinear configuration, wherein the cross-sectional configuration of the needle is cold-formed into varying shapes in order to produce a needle having superior physical characteristics and strengths imparted thereto through the process. The needles are essentially cold formed. The process includes the aspect of imparting to straight metal rods, which are preferably constituted from stainless steel, manufacturing steps which include sharpening one end of rod severed segments so as to form the needle tip, thereafter curving the needle with the metal still being in a relatively ductile state, and subjecting the needle to a cold forming process to produce varying cross-sectional shapes along the length of the needle.

In response to applicant's previously arguments, the Examiner has taken the position that:

> It would have been obvious to one of ordinary skill in the art a the time the invention was made to modify the combination of Yoon and Hubbard with a needle made of metal for non-endoscopic procedures such as suturing skin in order to provide a needle with sufficient strength to perform procedures without breakage or deformation.

As the Supreme Court declared in KSR International Co. v. Teleflex Inc., 550 U.S. __, 82 USPQ2d 1385 (2007), "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

It is respectfully submitted that the combination of a specific bioabsorbable suture device for use in endoscopic surgery with a disposable medicinal hypodermic syringe and a process for enhancing the physical strength of

conventional suture needles through a cold-forming procedure does not approach applicant's claimed invention. It is respectfully submitted that the Examiner's analysis ignores applicant's requirement that the suture needle have a yielding moment and an internal cavity wherein the suture needle possesses a non-linear relationship between the cross-sectional area of the internal cavity and the yielding moment. Nowhere in the relied upon references is this limitation fairly taught or suggested, as is required to support a case of prima facie obviousness. As instructed by the court in In re Evanega, 4 USPQ 2d 1249 (Fed. Cir. 1987), the mere absence [from a reference] of a specific requirement [of the claim] cannot be construed as an affirmative statement that [the requirement is in the reference].

Even assuming that the relied upon references disclosed each and every element of applicant's claimed invention, which, as indicated below, they do not, the KSR Court observed that a claimed invention comprised of several elements is not rendered obvious merely by showing that each of the elements was known in the prior art.

In formulating the instant rejection, the Examiner has posited that the suture needle of Yoon et al., produced from a bioabsorbable material, be replaced with one produced from metal tubing, a modification that would destroy the stated object and function of the Yoon et al. invention. As remains well-settled under the law, if a reference is cited that requires some modification in order to meet the terms of applicant's claimed invention and that modification would destroy the purpose or function of the invention disclosed in the relied-upon reference, one of ordinary skill in the art would find no reason to make the proposed modification. In re Gordon, at 221 USPQ 1127, 733 F.2d 902, that "the mere fact that the reference could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification."

Finally, the Examiner objected to the applicant's limitation "wherein the device is made of metal tubing," treating the language as a product by process limitation. The Examiner thus evaluated the claims "without giving much weight to the method of its manufacture." As may be seen the applicant has addressed this issue by amending claim 1 to now require a metal suture needle having a yielding moment and an internal cavity therein comprising: a proximal end, a distal end, a point on the distal end, an opening at or in the proximity of the distal end, and a non-hollow portion or seal at or adjacent to the proximal end; the internal cavity having a cross-sectional area and being in fluid communication with said opening at one end and terminates at said non-hollow portion or seal at the other end; a fluid residing within the internal cavity; and a compressed gas residing between the fluid and the non-hollow portion or seal, wherein the suture needle having a non-linear relationship between the cross-sectional area of the internal cavity and the yielding moment. It is respectfully requested that each of applicant's claim limitations be fully considered.

In view thereof, the applicant respectfully requests that the rejection of claims 1, 2 and 15 under 35 U.S.C. 103(a) as being unpatentable over Yoon et al., U.S. Patent No. 4,981,149, in view of Hubbard et al., U.S. Patent No. 3,308,820 and further in view of McGregor et al., U.S. Patent No. 5,649,961, be removed.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478(13925).

It is respectfully submitted that the present claims are in condition for allowance. Prompt notification of allowance is respectfully solicited.

Respectfully submitted,

Date: May 8, 2008

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